

*REMARKS/ARGUMENTS**Examiner Interview*

Applicants thank Examiner Calamita and her supervisor, Teresa E. Strzelecka, for the courtesy extended to their representative, Melissa E. Kolom, during the telephonic interview held on December 11, 2006. The matters discussed during the interview are substantially as set forth herein.

*The Pending Claims*

Claims 86, 88, 89, 92-94, 97, 100, 105, and 107 are pending and are directed to methods to detect the taxonomic unit of any species of enterobacteria, but no species of another taxonomic unit.

*The Amendments to the Claims*

Claims 86, 92, 100, and 105 have been amended to clarify that the nucleic acid sequence(s) of step (c) is (are) a *full* complement of SEQ ID NO: 2, SEQ ID NO: 78, a nucleic acid molecule which exhibits 90% identity with SEQ ID NO: 2, or a nucleic acid molecule which exhibits 90% identity with SEQ ID NO: 78. Accordingly, no new matter has been added by way of these amendments.

*The Office Action*

The Office Action rejects claims 86, 88, 89, 92-94, 97, 100, 105, and 107 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Office Action rejects claims 86, 88, 89, 92-94, 97, and 107 under 35 U.S.C. § 103 (a) as allegedly unpatentable over U.S. Patent 5,654,141 (Mariani et al.) ("the Mariani patent") in view of Yamamoto et al. (GenBank Accession Number AB001341, submitted January 25, 1997). Reconsideration of these rejections is hereby requested.

*Discussion of Written Description Rejection*

Claims 86, 88, 89, 92-94, 97, 100, 105, and 107 allegedly lack written description because the specification does not support a method for detecting any species of the

taxonomic unit of Enterobacteriaceae, and no species of another taxonomic unit, and because the specification does not disclose a representative number of species of complements of SEQ ID NOs: 2 and 78.

As discussed during the aforementioned Examiner interview, the specification clearly discloses a method of detecting Enterobacteria and no other taxonomic unit of bacteria. In particular, Table 1 of the specification is entitled "Detection of enterobacteria excluding other bacteria," and clearly demonstrates that the claimed method detects species of Enterobacteriaceae while excluding other species and taxa. Indeed, the Office Action itself acknowledges that Table 1 shows that "enterobacteria are completely delimited from representatives of other taxa" (Office Action at page 2, last paragraph). There are numerous other experiments disclosed in the specification which demonstrate that the claimed method detects species of Enterobacteriaceae and does not detect species of other taxa.

With respect to written description of the term "complement," Examiner Strzelecka indicated during the Examiner interview that this term encompasses a single nucleotide complementary to a particular nucleic acid sequence. On the other hand, the term "full complement" apparently encompasses a complete complementary sequence. Thus, as suggested by Examiner Strzelecka, claims 86, 92, 100, and 105 have been amended to clarify that the sequence recited in step (c) of each of the rejected claims is a full complement of SEQ ID NO: 2, SEQ ID NO: 78, a nucleic acid molecule which exhibits 90% identity with SEQ ID NO: 2, or a nucleic acid molecule which exhibits 90% identity with SEQ ID NO: 78. It is well known in the art that a full complement of a particular nucleic acid sequence is a unique sequence that can be determined using only routine methods in the art.

In view of the foregoing, Applicants submit that the Section 112, first paragraph, rejection of the claims as lacking adequate written description is improper and should be withdrawn.

#### *Discussion of Obviousness Rejection*

Claims 86, 88, 89, 92-94, 97, and 107 are rejected as allegedly obvious over the Mariani patent in view of GenBank Accession No. AB001341 (Yamamoto et al.). While the Office Action acknowledges that neither the Mariani patent nor the Yamamoto sequence

discloses a nucleic acid sequence consisting of SEQ ID NO: 2, the Examiner alleges that claims 86 and 92 only require that the *Markush group* recited therein consists of SEQ ID NO: 2 or SEQ ID NO: 78. As discussed during the Examiner interview, Applicants disagree with the Office Action's interpretation of claims 86 and 92. In this respect, claims 86 and 92 clearly recite a nucleic acid(s) selected from the group consisting of nucleic acid molecules *consisting of* at least one sequence of SEQ ID NOs: 2 and 78. Thus, claims 86 and 92, and claims depending therefrom, encompass the use of a nucleic acid molecule *consisting of* SEQ ID NO: 2, SEQ ID NO: 78, or a combination of SEQ ID NO: 2 and SEQ ID NO: 78.

Applicants also have previously argued that neither the Mariani patent nor the Yamamoto sequence discloses detecting any species of the taxonomic unit of Enterobacteriaceae, and no species of another taxonomic unit. The Office Action dismisses this argument because the preamble of the rejected claims allegedly does not limit the claim. As discussed during the Examiner interview, the step of detecting any species of Enterobacteriaceae to the exclusion of other species is recited not only in the preamble of claim 86, but also as the final step of the method recited therein. In addition, the step of detecting any species of Enterobacteriaceae to the exclusion of other species is not recited in the preamble of claim 92, but rather is an integral element of the method recited therein.


Applicants reiterate that none of the cited references discloses or suggests a method of detecting any species of the taxonomic unit of enterobacteria and no other taxonomic unit. In addition, none of the cited references discloses or suggests the use of a nucleic acid molecule *consisting of* SEQ ID NO: 2 or SEQ ID NO: 78, let alone a combination of nucleic acid molecules *consisting of* SEQ ID NOs: 2 and 78, or a combination of nucleic acid molecules as otherwise recited in the pending claims.

In view of the foregoing, the combined disclosures of the Mariani patent and Yamamoto et al. do not disclose or suggest the subject matter of the pending claims. As such, the obviousness rejection is improper and should be withdrawn.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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